

# COVID-19 Vaccine

Quick Reference Guide for  
Healthcare Professionals



## » Clinical Materials Update

On April 13, 2021, **CDC and FDA recommended a pause in the use of Janssen COVID-19 Vaccine (Johnson & Johnson)** out of an abundance of caution while they review data involving a small number of reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in individuals after receiving Janssen COVID-19 Vaccine (<https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>). The Advisory Committee on Immunization Practices (ACIP, <https://www.cdc.gov/vaccines/acip/index.html>) met on April 14. After hearing additional data on these reports, ACIP agreed that more information is needed before policy recommendations can be made regarding continued use of the Janssen COVID-19 vaccine. CDC will collect more information and convene another ACIP meeting on April 23 to review any additional scientific evidence.

**At this time, the recommended pause supersedes any other recommendations for use of Janssen COVID-19 Vaccine.**

Recommendations for clinicians related to the detection, evaluation, proper management, and reporting of cases of CVST with thrombocytopenia after receipt of Janssen COVID-19 Vaccine are outlined in Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>. These can also be found in CDC's Health Alert (<https://emergency.cdc.gov/han/2021/han00442.asp>) , issued April 13.

### **If you are a COVID-19 vaccination provider with Janssen COVID-19 Vaccine:**

1. Mark any Janssen COVID-19 Vaccine in your inventory "Do not use. Awaiting guidance."
2. Continue to store the vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
3. Continue to monitor and document storage unit temperatures and follow recommended vaccine storage practices.

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The table below provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. For additional information and detailed clinical guidance go to the manufacturer's and CDC's webpages listed.

		Pfizer	Moderna	Janssen
GENERAL	EUA	<a href="https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine">www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine</a>	<a href="https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine">www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine</a>	<a href="https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine">www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine</a>
	CDC Vaccine Information	<a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html">www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html</a>	<a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html">www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html</a>	<a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html">www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html</a>
	Manufacturer Contact information	Website: <a href="https://www.cvdvaccine.com">www.cvdvaccine.com</a> Medical information: 800-438-1985 Customer service: 800-879-3477	Website: <a href="https://www.modernatx.com">www.modernatx.com</a> Medical Information: 866-663-3762	Website: <a href="https://www.vaxcheck.jnj.com">www.vaxcheck.jnj.com</a> Medical information: 1-800-565-4008
STORAGE & HANDLING	How supplied	<b>Multidose vial:</b> 6 doses	<b>Multidose vial:</b> Maximum of 11 doses	<b>Multidose vial:</b> 5 doses
	Diluent	0.9% sodium chloride (preservative-free, normal saline) provided in the ancillary kit. Do NOT use other diluent.	None	None
	Storage Temperatures: Before Puncture	<b>Between:</b> -80°C and -60°C (-112°F and -76°F) until the expiration date -25°C and -15°C (-13°F and 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days)	<b>Between:</b> -50°C and -15°C (-58°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days 8°C and 25°C (46°F and 77°F) for a total of 24 hours	<b>Between:</b> 2°C and 8°C (36°F and 46°F) until the expiration date.
	Storage Temperatures: After puncture	<b>Between:</b> 2°C to 25°C (36°F to 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.	<b>Between:</b> 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.	<b>Between:</b> 2°C and 8°C (36°F and 46°F) for up to 6 hours. 9°C and 25°C (47°F and 77°F) for up to 2 hours. Discard any unused vaccine after these time frames.
	Transport Temperatures: Before Puncture	<b>Between:</b> -80°C and -60°C (-112°F and -76°F) -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F)	<b>Between:</b> -50°C and -15°C (-58°F and 5°F) 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours.	<b>Between:</b> 2°C and 8°C (36°F and 46°F)
	Transport Temperatures*: After Puncture	<b>Between:</b> 2°C to 25°C (36°F to 77°F) for up to 6 hours.	<b>Between:</b> 2°C and 25°C (36°F and 77°F) for up to 12 hours.	<b>Between:</b> 2°C and 8°C (36°F and 46°F) for up to 6 hours
	Type of Vaccine	mRNA	mRNA	Viral vector
	Age Indications	16 years of age and older	18 years of age and older	18 years of age and older
	Schedule	2-doses, separated by 21 days. Both doses must be Pfizer-BioNTech vaccine	2 doses, separated by 28 days. Both doses should be Moderna vaccine	1 dose only
	Dosage	0.3 mL	0.5 mL	0.5 mL
	Needle gauge/length	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"	22–25 gauge, 1 – 1½"

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		Pfizer	Moderna	Janssen
V A C C I N E  A D M I N I S T R A T I O N	Route	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
	Site	Deltoid	Deltoid	Deltoid
	Thawing Frozen Vaccine	<b>Between:</b> 2°C and 8°C (36°F and 46°F) or Room temperature up to 25°C (77°F) <b>Do NOT</b> refreeze thawed vaccine.	<b>Between:</b> 2°C and 8°C (36°F and 46°F) or 8°C to 25°C (46°F to 77°F) <b>Do NOT</b> refreeze thawed vaccine.	N/A
	Mixing Vaccine	Mix vaccine with 1.8 mL of 0.9% sodium chloride (preservative-free, normal saline)	<b>Do NOT</b> mix with any diluent	<b>Do NOT</b> mix with any diluent
	Contraindications/ Precautions	<b>Contraindications</b> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine</li> <li>Immediate allergic reaction† of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine</li> </ul> <b>Note:</b> Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).‡ Persons who have a contraindication to Janssen COVID-19 vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).‡ <b>Precautions</b> <ul style="list-style-type: none"> <li>History of an immediate allergic reaction† to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)               <ul style="list-style-type: none"> <li>» This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.</li> </ul> </li> <li>People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa. (see footnote).‡</li> <li>Moderate to severe acute illness</li> </ul> See Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html">www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</a>		
	Post-Vaccination Observation	<b>30 minutes:</b> Persons with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy or a history of anaphylaxis (from any cause) <b>15 minutes:</b> All other persons		
	Most common adverse events	<b>Injection site:</b> pain, swelling, redness <b>Systemic:</b> fatigue, headache, muscle pain, chills, fever, joint pain	<b>Injection site:</b> pain, swelling, redness <b>Systemic:</b> fatigue, headache, muscle pain, chills, fever, nausea, joint pain	<b>Injection site:</b> pain, redness, swelling <b>Systemic:</b> fatigue, headache, muscle pain, nausea, fever

†For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

‡Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVID vax Project <https://www.cdc.gov/vaccinesafety/ensuring-safety/monitoring/cisa/index.html>. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose but have a contraindication to a second dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.